North Carolina, and Michigan. The article was labeled in part: (Ampul) "0.15 Gm. * * * Doryl * * * (Carbamylcholine Chloride Merck)."

Examination showed that the article possessed the composition declared on its label.

The article was alleged to be misbranded (1) in that the labeling of the article was misleading since the boxes and cartons containing the ampuls and the ampul labels bore the statement "Do Not Use Intravenously," which suggested and implied that other methods of injection were safe and appropriate, whereas other methods of injection were not safe and appropriate, and the labeling of the article failed to reveal the fact, material in the light of such labeling, that the article was lethal when injected by any method; (2) in that the directions for use which appeared on the labeling of the article, "Do Not Use Intravenously" and "Sufficient to make 20 cc. of a 0.75% Solution for Ophthalmologic Use," were inadequate since they failed to reveal that the article was not to be used for injection by any method, but only in solutions for ophthalmologic use; (3) in that the labeling of the article failed to warn against injection other than intravenously; and (4) in that its container was so made, formed, and filled as to be misleading since the container was in a form in which drugs intended for injection are customarily packaged.

On February 2, 1945, a plea of nolo contendere having been entered on behalf of the defendant, the court imposed a fine of $1,000 on each of 15 counts in the indictment, a total fine of $15,000.

1352. Misbranding of Doryl. U. S. v. 10 Ampuls of Doryl (and 3 other seizure actions against Doryl). Default decrees of condemnation and destruction. (F. D. C. Nos. 11498, 11501 to 11503, incl. Sample Nos. 51265–F, 51266–F, 51571–F, 51575–F.)

On December 27 and 28, 1943, the United States attorney for the District of Massachusetts filed libels against 19 ampuls of Doryl at Boston, Mass., and 4 ampuls of Doryl at Woburn, Mass., alleging that the article had been shipped by Merck & Co., Inc., from Rahway, N. J., between the approximate dates of March 11 and May 11, 1943. The article was labeled in part: "0.15 Gm. Ampul * * * Doryl (Carbamylcholine Chloride Merck) Do not use intravenously. * * * Sufficient to make 20 cc. of a 0.75% Solution for Opthalmologic Use."

The article was alleged to be misbranded (1) in that its labeling failed to bear adequate directions for use since the statements in the labeling, "Do not use intravenously" and "for Ophthalmologic Use," were inadequate since they failed to reveal that the article was intended not to be used for injection, but only in solution for ophthalmologic purposes; (2) in that its labeling failed to bear adequate warnings since the labeling did not clearly warn that the preparation was not intended for injection and would be lethal if so used; (3) in that the statement "Do not use intravenously," appearing in the labeling of an article packaged in ampul form, was misleading since it suggested that the article was suitable for injection otherwise than intravenously, whereas the article, when injected, would cause death; and (4) in that its container was so made, formed, and filled as to be misleading since it was in a form in which drugs intended for injection are sometimes packaged.

On March 12, 1945, no claimant having appeared, judgments of condemnation were entered and the product was ordered destroyed.

1353. Misbranding of Salvitae, Salugen, and Syrup of Ambrozoin. U. S. v. American Apothecaries Co., Inc. Plea of guilty. Fine, $400. (F. D. C. No. 6423. Sample Nos. 51112–E, 51114–E, 51115–E.)

On June 28, 1943, the United States attorney for the Eastern District of New York filed an information against the American Apothecaries Co., Inc., Long Island City, N. Y., alleging shipment of a quantity of the above-named products on or about March 10, 1941, from the State New York into the State of Massachusetts.

Analysis of a sample of the Salvitae disclosed that it consisted essentially of sodium sulfate, magnesium sulfate, sodium bicarbonate, compounds of lithium, potassium and sodium, and strontium, carbonates, citrates, tartrates, caffeine, and methenamine. The article was alleged to be misbranded because of false and misleading statements in its labeling which represented and suggested that it would be an effective aid in the treatment of gingivitis, soft, bleeding gums, receding gums, and for conditions due to a deficiency in the alkalinity of the salivary secretions; that the article would augment, stimulate, and encourage the natural activity of the eliminative organs; that it would promote metabolism; that it

would aid individuals to remain physiologically correct; that it would aid metabolism to draw heavily upon the mineral elements for the neutralization of acid, maintenance of electrolyte concentrations of the body fluid, evolvement of bony tissue, and the sustentation of a proper physiology in individuals who, having given up an active life for a sedentary one, maintain or increase their food consumption but fail to expend resultant potential energy; that it would prevent tetany and parathyroid insufficiency by preventing the deprivation of calcium; that it would promote the concentration of magnesium and thereby prevent the development of muscular incoordination, convulsions, and death; that it would prevent lack of sufficient calcium and phosphorus and thereby prevent the restriction of the growth of bones and the production of osteoporosis of the long bones; that it would supply potassium and magnesium and thereby maintain osmotic pressure in both intracellular and extracellular fluids, the regulation of physiological neutrality, and a proper irritability of the heart muscles; that it would supply those minerals, the deficiency of which is the cause, in whole or in part, of rickets, prolonged postpartum invalidism, chronic asthenia, pellagra, and sprue; that it would prevent disturbance of the acid base equilibrium and the removal of a natural defense in the body against diabetes, gout, obesity, arthritis, and various infective disorders; that it was an efficient mineralizing and antacid measure; that it was a scientifically balanced combination of the salts of potassium, magnesium, calcium, strontium, sodium, and lithium, so quantitatively formulated as to provide the highest therapeutic efficiency; that it would aid in the elimination of waste products by accelerating the excretion of the uric aid in cases of gout, by promoting the oxidation of carbohydrates in cases of diabetes, and by raising the lowered metabolism that is responsible for obesity; that it would aid in discharging the toxic load of gout, diabetes, and obesity; that it would be insurance against the predisposition of systemic hyperacidity to the occurrence of rhinitis, grippe, influenza, bronchitis, and other infectious disorders of the upper respiratory tract; that it would be efficacious in the cure, mitigation, treatment, or prevention of acidity as evidenced by constipation, headaches, and biliousness; that it would replenish mineral deficiencies, act as a catalyzer for chemical reactions in processes of absorption, retention, and utilization, promote vigor of muscle and integrity of bone structure, enter into the intermediate metabolism of the endocrines, and sustain the alkalinity of the blood; that it would be efficacious in the prevention of acid intoxication and undue systemic acidity and the retention of toxic products which cause rheumatic pains, colds, headaches, undue nervousness, and chronic constipation; that it would remove from the urine all the end products of metabolism; that it would be efficacious in the cure, treatment, mitigation, or prevention of gastric hyperchlorhydria, cachexias, endocrine disturbances, and chronic atonic states; and that it would promote metabolism during pregnancy and following delivery, in the rachitis of childhood, in convalescence from exhausting diseases such as fever and pneumonia, and in invalidism. The article would not accomplish the results suggested and implied in its labeling. It was alleged to be misbranded further in that its label failed to bear adequate directions for use since the label failed to limit the duration for which the article might be taken; and in that its label failed to warn against the use of the article in cases of abdominal pain, nausea, vomiting, and other symptoms of appendicitis, and against frequent or continual use when such use might result in dependence upon cathartic drugs to move the bowels.

Analysis of a sample of the Salugen showed that it consisted essentially of boric acid, betanaphthol, compounds of aluminum, zinc and small proportions of thymol, eucalyptol and menthol, an alkaloid-bearing drug, flavoring material, and water. Bacteriological examination showed that the article was not antiseptic when diluted as recommended in the labeling. The article was alleged to be misbranded because of false and misleading statements in its labeling which represented and suggested that the article was a disinfectant; that, when used as a wet dressing, it would be efficacious in the treatment of abrasions, burns, chafing, chronic sores, cuts, insect bites, stings, and scalds; that it would be efficacious as a douche, gargle, and spray, and as an internal remedy in diarrhea, dysentery, and excessive intestinal fermentation; that it would be a general antiseptic and prophylactic; that it would help to destroy germ life, arrest hemorrhage, prevent suppuration, dispel wound fetor, and promote healing without endangering human life or irritating delicate tissues; that, when used as a mouth wash or dentifrice, it would help prevent decay of teeth, invigorate the gums checkmate recession, and render the oral cavity germ-free; that it would be efficacious in the treatment of acute or chronic catarrhal affections of the nose, throat, or nasal passages, gonorrhea, leucorrhea, vaginitis, and diseases of the genito-

urinary tract, various eruptive affections of the skin, such as ivy poisoning, urticaria, eczema, impetigo, and prurigo, and accidental wounds, such as abrasions, cuts, and bruises; that it would help to prevent infection, diminish pain, and expedite repair; that it would be efficacious in the treatment of old sores, abscesses, ulcers, and suppurating wounds, and would stimulate granulation; that it would be efficacious in the treatment of fetid discharge from pus cavities and external wounds; that, when used as directed, it would be efficacious in the treatment of tonsilitis, laryngitis, pharyngitis, and sore throat, acute and chronic nasal catarrh, gingivitis of local or systemic origin, and spongy, bleeding, or receding gums; that the article would impart tone and firmness to the gums, would help prevent the decay of teeth, would normalize the salivary secretions, would prevent fermentative processes, and would tone the oral activity; and that it would be efficacious in preventing fetid breath and the spread of such contagious diseases as scarlet fever, smallpox, chickenpox, and measles, in disinfecting all discharges from a patient suffering from a contagious disease, in treating eruptive affections of the skin and an inflammatory condition of the skin caused by undue exposure to the sun, wind, or frost, in treating various intestinal disorders arising from the ingestion of unripe fruit, tainted meats or vegetables, sour or impure milk, or other unwholesome foodstuffs, and in treating intestinal fermentation involving diarrheal or dysenteric symptoms The article would not accomplish the results suggested and implied in its labeling.

Analysis of a sample of the Syrup of Ambrozion disclosed that the article consisted essentially of terpene hydrate, guaiacol, ammonium chloride, compounds of sodium and potassium, a small proportion of alkaloid such as sanguinarine, sugar, and water. The article was alleged to be misbranded because of false and misleading statements in its labeling which represented and suggested that the article would be efficacious in the treatment of acute and chronic inflammatory affections of the upper respiratory passages where cough, labored breathing, lessened expectoration, and pain are disturbing factors; that it would aid in allaying respiratory hyper-sensitiveness; that it would overcome the feeling of tightness or suffocation by aiding the expulsion of mucous from the air passages, and would allay pain due to expulsive efforts; that it would be useful in acute and chronic bronchitis because it would increase the fluidity of bronchial secretions, stimulate expectoration, and exert a soothing influence on the bronchial mucous membrane; that it would tend to prevent the accumulation of mucous in the air passages of persons of advanced age suffering from chronic bronchitis, and thus render respiration less difficult or discomforting; that it could be used to distinct advantage as both a prophylactic and palliative in acute attacks of bronchitis, such as frequently follow exposure to cold or dampness; that it would be beneficial in the treatment of asthma; that, when used as soon as symptoms of an impending seizure of hay fever were experienced, it would be efficacious in preventing the development of an attack of hay fever; that it would be efficacious in cases of whooping cough, in diminishing the number and severity of paroxysms, in facilitating expectoration, and in tending to allay the nervousness of the patient; that it would render the patient less liable to attacks of vomiting after paroxysms of whooping cough, and would promote sleep; that the article would be advantageous in the prevention of attacks of cold, bronchitis, laryngitis, or other inflammatory affections of the respiratory tract in persons predisposed to such attacks; and that it would be efficacious in the cure, mitigation, treatment, or prevention of inflamed mucous membranes of the throat. The article would not accomplish the results suggested and implied in the labeling.

On October 11, 1944, the defendant having entered a plea of guilty, the court imposed a fine of $100 on 1 count and $150 on each of 2 other counts, a total fine of $400.

1354. Misbranding of herb remedies. U. S. v. Alta C. Meskell. Plea of guilty. Fine, $250. Sentence of 6 months' imprisonment suspended, and defendant placed on probation for 5 years. (F. D. C. No. 11417. Sample Nos. 17792–F, 17793–F, 33817–F to 33821–F, incl., 34014–F, 34015–F.)

On July 24, 1944, the United States attorney for the Middle District of Pennsylvania filed an information against Alta C. Meskell, Williamsport, Pa., alleging shipment on or about February 2 and April 18, 1943, from the State of Pennsylvania into the State of New York of a quantity of herb remedies referred to as No. 16–1, No. 21–01, Meskell's Special Compound No. 1–2–3, No. 120–00S Compound, No. 990 Laxative, No. 9990–B–T, No. 7., No. 1116, and No. 1321.

Analysis of the No. 16–1 showed that it consisted essentially of plant material including fennel seed, rosemary leaves, juniper berries, althaea root, sweet